

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference SPE 00257/WO	FOR FURTHER ACTION	See item 4 below
International application No. PCT/EP2004/012295	International filing date (<i>day/month/year</i>) 29 October 2004 (29.10.2004)	Priority date (<i>day/month/year</i>) 30 October 2003 (30.10.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SPINTEC ENGINEERING GMBH		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 01 May 2006 (01.05.2006)
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PATENT COOPERATION TREATY

REC'D 18 AUG 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

AP

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2004/012295

International filing date (day/month/year)
29.10.2004

Priority date (day/month/year)
30.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61L15/32, A61K38/17, C07K14/435

Applicant
SPINTEC ENGINEERING GMBH

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012295

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/EP2004/012295

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, Inventive step or Industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	33,40,49-53,58-72,77
	No: Claims	1-32,34-39,41-48, 54-57,73-76,78
Inventive step (IS)	Yes: Claims	
	No: Claims	1-78
Industrial applicability (IA)	Yes: Claims	1-78
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Comments on item V

1. The documents cited in the International Search Report correspond respectively to D1-D5. Any reference to the documents in the present written opinion relates to the passages given in said report, unless otherwise indicated.

D1: ALTMAN G H ET AL: "Silk-based biomaterials" BIOMATERIALS, ELSEVIER SCIENCE PUBLISHERS BV., BARKING, GB, vol. 24, no. 3, February 2003 , pages 401-416

D2: ZHANG Y-Q: "Applications of natural silk protein sericin in biomaterials" BIOTECHNOLOGY ADVANCES, ELSEVIER PUBLISHING, BARKING, GB, vol. 20, no. 2, May 2002, pages 91-100

D3: HIRANO S ET AL: "Chemical Modification and some Aligned Composites of Chitosan in a Filament State" MACROMOLECULAR BIOSCIENCE 15 OCT 2003 GERMANY, vol. 3, no. 10, 15 October 2003, pages 620-628

D4: US 2003/087433 A1

D5: OKAMOTO H ET AL: "STRUCTURAL ANALYSIS OF SERICIN GENES HOMOLOGIES WITH FIBROIN GENE IN THE 5' FLANKING NUCLEOTIDE SEQUENCES" JOURNAL OF BIOLOGICAL CHEMISTRY. (MICROFILMS), AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 257, no. 24, 25 December 1982, pages 15192-15199

2. According to the present description, the applicants have carried out research work for improving their knowledge on the properties of sericin. Starting with Bombyx cocoons, they have verified that fibroin brins are cemented together by sericin, they have studied the proportion of serin in the sericin sequence and they have seen that silkworm silk cocoons are composite materials stiffened by sericin in the glassy state. There are, however, no examples/explanations referring to the subject-matter actually claimed. The claims, which are very broad, cover hundred of possible embodiments which are not supported by the description in the sense that no particular combination of polymers and sericin are described and therefore the skilled person would not know which technical effect may be associated to each possible type of sericin matrix.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/EP2004/012295

Not all the embodiments covered by the claims were known in the art at the date of filing (see the International Search Report concerning the specific claims anticipated by each document), but the information provided by the present description was indeed known (see, for instance, D1 or D2 concerning general aspects of sericin and D5 concerning the amino acid sequence of sericin), which means that there seems to be no new teaching provided by the present International application.

Comments on item VII

3. The requirements of Articles 5 and 6 PCT are not met, since the subject-matter of claims 1-78 is not supported by the description in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Furthermore, the scope of the claims is broader than justified by the description and drawings.